K031648

JUL 24 2003

# SMDA 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

## A. GENERAL INFORMATION

### 1. Applicant

Olympus Optical Co., Ltd.
34-3 Hirai Hinode-machi,
Nishitama-gun, Tokyo, 190-0182
Japan
(Registration Number: 3003637092)

### 2. Submission Correspondence

Olympus Optical Co., Ltd.
2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507, JAPAN
TEL: +81-426-42-5129
FAX:+81-426-42-9979
(Registration Number: 8010047)

### 3. Official Correspondent

Tina Steffanie-Oak, Senior R.A. Analyst
Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-3157
TEL: 631-844-5477
FAX: 631-844-5416
(Registration Number:2429304)

## B. DEVICE IDENTIFICATION

### 1. Common/Usual Name

RHINO-LARYNGOVIDEOSCOPE, its accessories and ancillary equipment

### 2. Device Name

VISERA RHINO-LARYNGOVIDEOSCOPE OLYMPUS ENF TYPE V, its accessories and ancillary equipment

### 3. Classification Name

| CFR Number | Classification Name | Class | Product Code |
|---|---|---|---|
| 874.4760 | Nasopharyngoscope (flexible) and accessories | II | EOB |

## C. IDENTIFICATION OF LEGALLY MARKETED DEVICES WHICH WE CLAIM SUBSTANTIAL EQUIVALENCE

| Model | 510(k)# | Manufacturer | Class | Product Code |
|---|---|---|---|---|
| VISERA Rhino-Laryngovideoscope Olympus ENF type V | #K021073 | Olympus Optical Co., Ltd. | II | EOB |
| EVIS EXERA Bronchovideoscope Olympus BF type 3C160 | #K023984 | Olympus Optical Co., Ltd. | II | EOQ |

## D. DEVICE DESCRIPTION

### 1. Summary

The subject device, the VISERA Rhino-Laryngovideoscope Olympus ENF type V is identical to the predicate device cleared in #K021073. This premarket notification is submitted to expand the intended use to add compatibility with strobe light sources specified by Olympus and change the applications from the nasal and nasopharyngeal lumens to the nasal lumens and airway anatomy. Olympus specifies the Light Source Model 9100 B and 9100 C (#K921184) manufactured by Kay Elemetrics corp., for endoscopic diagnosis using the strobe light source.

### 2. Design

The VISERA Rhino-Laryngovideoscope Olympus ENF type V has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC60601-1, IEC60601-1-1, IEC60601-1-2 and IEC60601-2-18.

### 3. Materials

All the patient contacting materials used in this endoscope and ancillary equipment are identical to those used in the devices cleared in the past 510(k) submissions. All materials have been confirmed with ISO 10993-1.

### 4. Intended Use of the device

This instrument has been designed to be used with an OLYMPUS video system center, light source, documentation equipment, display monitor, strobe light source specified by OLYMPUS, and ancillary equipment for endoscopic diagnosis within the nasal lumens and airway anatomy.

### 5. Summary including conclusion drawn form Non-clinical Tests

When compared to the predicate device, the ENF-V does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect safety and effectiveness. Therefore clinical data is not necessary for evaluation of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2003

Olympus Optical Co., Ltd.
c/o Tina Steffanie-Oak, Senior R.A. Analyst
Olympus America Inc.
Two Corporate Center Dr.
Melville, NY 11747

Re: K031648
Trade/Device Name: Visera Rhino-Laryngovideoscope Olympus ENF Type V
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: May 23, 2003
Received: May 28, 2003

Dear Ms. Steffanie-Oak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not assigned yet K031648

Device Name: VISERA RHINO-LARYNGOVIDEOSCOPE OLYMPUS ENF TYPE V

Indications for Use:

This instrument has been designed to be used with an OLYMPUS video system center, light source, documentation equipment, display monitor, strobe light source specified by OLYMPUS, and ancillary equipment for endoscopic diagnosis within the nasal lumens and airway anatomy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K031648